IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.	:	09/692,634
Inventor(s)	:	Rennie, Paul John et al.
Filed	:	October 19, 2000
Art Unit	:	1617
Examiner	:	Cruz, Kathrien Ann
Docket No.	:	8308
Confirmation No.	:	8314
Customer No.	:	27752
Title	:	Compositions For Prevention And Treatment Of Cold And Influenza-Like Symptoms And Their Methods Of Use

APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

This Brief is filed pursuant to the appeal from the decision communicated in the Office Action mailed on November 13, 2008 finally rejecting Claims1, 4-7, 20-22, 26, 27, 54 and 57-60. A timely Notice of Appeal was filed on January 27, 2009. Attached hereto is a Petition for a Three-Month Extension of Time, providing for a timely response up to and including June 27, 2009. All related fees are to be charged to the Assignee's Deposit Account #16-2480.

REAL PARTY IN INTEREST

The real party in interest is The Procter & Gamble Company of Cincinnati, Ohio.

RELATED APPEALS AND INTERFERENCES

There are no known related appeals, interferences, or judicial proceedings.

STATUS OF CLAIMS

Claims 1, 4-7, 20-22, 26, 27, 54 and 57-60 are finally rejected. Claims 1, 4-7, 20-22, 26, 27, 54 and 57-60 are appealed.

A complete copy of the appealed claims is set forth in the Claims Appendix attached herein.

STATUS OF AMENDMENTS

No amendment was filed.

SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is directed to a method for treating cold or influenza viruses (page 4, lines 5-7) wherein the method comprises the step of spraying into the nasal turbinates(page 4, lines 20-23, page 5, lines 5-6) a composition comprising: from about 1% to about 20% pyroglutamic acid (page 5, lines 13-14, and page 6, lines 7-9) and from about 0.01% to about 10% organic acid (page 6 lines 11-12 page 5 lines 15-17) having a dissociation constant (pKa) value from about 3.0 to about 5.0 (page 6 lines 12-13); and a pH adjusting agent (page 6 lines 28-30); wherein said composition has a pH of less than 4.5(page 6, lines 25-26); wherein the composition is a homogeneous liquid solution(page 7 line 27) having a pH value from about 3.5 to about 5.5 on the nasal tissues (page 6 lines 26-28).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

(I) Claims 1, 4-7, 20-22, 26, 27, 54 and 57-60 are rejected under 35 USC 103(a) over Deihi (EP0505374B1), in view of Makino et al. (US Patent No. 4789667) and further in view of Kuhrt et al. (Virucidal Activitiy of Glutaric Acid and Evidence for Dual Mechanism of Action, Antimicrobial Agents and Chemotherapy, Dec. 1984, pp. 924-927).

ARGUMENTS

THE APPLICATION OF DEIHI (EP0505374B1), IN VIEW OF MAKINO ET AL. (US PATENT NO. 4789667) AND FURTHER IN VIEW OF KUHRT ET AL. (VIRUCIDAL ACTIVITIY OF GLUTARIC ACID AND EVIDENCE FOR DUAL MECHANISM OF ACTION, ANTIMICROBIAL AGENTS AND CHEMOTHERAPY, DEC. 1984, PP. 924-927) DOES NOT RENDER OBVIOUS APPELLANTS' METHOD

Claims 1, 4-7, 20-22, 26, 27, 54, and 57-60 have been finally rejected under 35 USC §103(a) as being unpatentable over Deihi (EP0505374B1), in view of Makino et al. (US Patent No. 4789667) and further in view of Kuhrt et al. (Virucidal Activitiy of Glutaric Acid and Evidence for Dual Mechanism of Action, Antimicrobial Agents and Chemotherapy, Dec. 1984, pp. 924-927). The Examiner states that Deihl discloses a pharmacological composition for the treatment of the common cold by spraying said composition into the oral cavity. The composition comprises vitamin C and a non-toxic zinc salt. The Examiner states that Makino discloses a pharmaceutical composition for external use with enhanced pharmacologically active agent through the skin and that the composition comprises a pharmacologically active agent and an optically active or inactive pyroglutamic acid ester. The Examiner then states that Kuhrt discloses that Rhinovirus as a group is notably sensitive to inactivation in solutions with a pH of less than 5.3. Appellants respectfully traverse this rejection based on the remarks contained herein.

"The citing reference that merely indicate[s] that isolated elements and/or features recited in the claims are known is not sufficient basis for concluding that the combination of claimed elements would be obvious." See Ex parte Hiyamizu, 10 U.S.P.Q. 2D (BNA) 1393, 1394 (1988). There should be something in the prior art or a convincing line of reasoning in the answer suggesting the desirability of combining the reference in such a manner as to arrive at the claimed invention. Note In re Dembiczak 175 F. 3d 994, 999 (Fed. Cir. 1999). "[A] patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be **important** to identify **a reason** that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way claimed new invention does. This is so because **inventions in most, if not all, instances rely upon building blocks since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.**" KSR, 1727 S. Ct. 1727, at 1741 (2007) (emphasis added). A quote acknowledging a "helpful insight" by the Court of Customs and Patent Appeals when that court first established TSM. "Often, it will be

necessary for a court to look to interrelated teachings of multiple patents; . . . **to determine whether there was an apparent reason** to combine the known elements in the fashion claimed by the patent at issue." KSR, 1727 S. Ct. at 1740-41 (emphasis added).

Deihl discloses a composition that provides vitamin C in the manufacture of a pharmacological composition that can be used to treat common colds. Diehl does not teach or suggest a method for treating cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: from about 1% to about 20% pyroglutamic acid and from about 0.01% to about 10% organic acid organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues. Deihl specifically excludes nasal administration by calling out that the invention "is concerned with treatment of the common cold by spraying a pharmacological composition into the oral cavity" See Page 2, lines 24-28. Example V specifies that the compositions are sprayed " every two hours during wakeful periods into the mouths of patients" Additionally, Deihl never teaches or suggest a pH or that the pH of the nasal tissue when the solution is delivered to the nasal tissue is 3.5 to about 5.5 on the nasal tissue or a dissociation constant (pKa) value from about 3.0 to about 5.0. The Examiner relies on the "Dissociation Constants of Organic Acids and Bases, in CRC Handbook of Chemistry and Physics, Internet Version 2007(87th Edition)., to provide support for the inherency of the compounds properties, however, the Examiner cannot rely on this reference, since the current application has a file date of October 19, 2000. Additionally, Deihl never teaches or suggest that the pharmacological composition comprise a pH adjusting agent or pyroglutamic acid.

Makino discloses a pharmaceutical composition for external use that provides for enhanced penetration or permeation of drugs. Makino discloses that pyroglutamic acids can be used to aid in penetration of the drug through the external topical skin or mucosa of a warm blooded animal. Makino fails to teach or suggest a method for treating the cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: from about 1% to about 20% pyroglutamic acid and

~~an~~ from about 0.01% to about 10% organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein said composition has a pH of less than 4.5; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues.

The present invention utilizes pyroglutamic acid in combination with organic acids to create a hostile environment on the surface of the nasal cavity not for the delivery of drug that penetrate a mucosa. The Examiner's suggested modification would render the prior art unsatisfactory for its intended purpose. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741, 82 USPQ2d 1385, 1396 (2007).

Kuhrt discloses a study to determine if the virucidal activity of glutaric acid is solely due to low pH of a solution in which it is tested or to the intrinsic property of the chemical entity. Kuhrt discloses in the summary of the test that glutaric acid appears to inactive RV-14 and several other strains of human rhinovirus by a mode of action independent of acidic pH at low temperatures and that the aciduant effect at room temperature is not detectable. (See page 927, last paragraph). Kuhrt does not teach or suggest a method a treating the common cold with a composition that comprises pyroglutamic acid and an organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues. Kuhrt does not teach or suggest a homogeneous solution that has a pH of 3.5 to about 5.5 on the nasal tissue.

Assuming *arguendo* that one having ordinary skill in the art would combine the disclosures of Deihl, Maniko et al. and Kuhrt et al., one would still fall short of the of Appellants' claimed invention only to arrive at a composition for the mouth that comprises vitamin C, glutaric acid and zinc that utilizes pyroglutamic acid to enhance drug delivery and inactivates RV-14 and several other strains of human rhinovirus by a mode of action independent of acidic pH at low temperatures.

The combination of Deihl, Maniko et al. and Kuhrt et al., do not teach or suggest each and every element of Appellants' presently claimed invention i.e. A method for treating cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: from about 1% to about 20% pyroglutamic acid and ~~an~~ from about 0.01% to about 10% organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein said composition has a pH of less than 4.5; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues.

Accordingly, Claims 1, 4-7, 20-22, 26, 27, 54 and 57-60 are novel over the prior art of record. Reconsideration and withdrawal of the rejection on this basis are requested.

SUMMARY

In view of all of the above, it is respectfully submitted that the aforementioned rejections are erroneous. The Board's reversal of the rejections is respectfully requested.

Respectfully submitted,
THE PROCTER & GAMBLE COMPANY

/Cynthia L. Clay/
Signature
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CLAIMS APPENDIX

Claim 1 A method for treating cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: from about 1% to about 20% pyroglutamic acid and from about 0.01% to about 10% organic acid having a dissociation constant (pKa) value from about 3.0 to about 5.0; and a pH adjusting agent; wherein said composition has a pH of less than 4.5; wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues.

Claim 4 The method according to claim1wherein the organic acid is selected from the group consisting of ascorbic acid, mono-, di-, tri-carboxylic acids and mixtures thereof.

Claim 5 The method according to claim 4 wherein the organic acid is selected from the group consisting of salicylic, fumaric, benzoic, glutaric, lactic, citric, malonic, acetic, glycolic, malic, adipic, succinic, aspartic, phthalic, tartaric, glutamic, gluconic, and mixtures thereof.

Claim 6 The method according to claim 1 wherein the composition further comprises a mucoadhesive agent wherein the viscosity of the final composition is less than about 1000 cps wherein the composition has a pH of about 3.5.

Claim 7 The method according to claim 6 wherein the mucoadhesive agent is selected from the group consisting of carboxypolymethylene, carboxyvinyl polymers, homopolymers of acrylic acid crosslinked with an allyl ether of pentaerythritol, homopolymers of acrylic acid crosslinked with an allyl ether of sucrose, homopolymers of acrylic acid crosslinked with divinyl glycol, and mixtures thereof.

Claim 20 The method according to claim 1 wherein the composition further comprises salts of metals selected from the group consisting of: zinc, copper, tin, silver, iron, aluminum, nickel, cobalt, manganese, and mixtures thereof.

Claim 21 The method according to claim 20 wherein the metal salt is at a level from about 0.01% to about 10% by weight of the composition.

Claim 22 The method according to claim 21 wherein the metal salt is selected from the group consisting of acetates, ascorbates, chlorides, benzoates, citrates, gluconates, glutarates, lactates, malates, malonates, salicylates, succinates, and combinations thereof.

Claim 26 The method according to claim 20 comprising a mucoadhesive agent wherein the viscosity of the final composition is less than about 1000 cps wherein the composition has a pH of about 3.5.

Claim 27 The method according to claim 26 wherein the mucoadhesive agent is selected from the group consisting of carboxypolymethylene, carboxyvinyl polymers, homopolymers of acrylic acid crosslinked with an allyl ether of pentaerythritol, homopolymers of acrylic acid crosslinked with an allyl ether of sucrose, homopolymers of acrylic acid crosslinked with divinyl glycol, and mixtures thereof.

Claim 54 The method according to claim 1 wherein the pH adjusting agent is selected from the group consisting of: sodium bicarbonate, sodium phosphate, sodium hydroxide, ammonium hydroxide, sodium stannate, triethanolamine, sodium citrate, and mixtures thereof.

Claim 57 A method for treating cold or influenza viruses wherein the method comprises the step of spraying into the nasal turbinates a composition comprising: pyroglutamic acid, wherein the pyroglutamic acid is at a level from about 1% to about 20% by weight of the composition;

from about 0.01% to about 10% organic acid organic acid selected from the group consisting of: ascorbic acid, citric acid, and mixtures thereof;
a pH adjusting agent; wherein said composition has a pH of less than 4.5; and
wherein the composition is a homogeneous liquid solution having a pH value from about 3.5 to about 5.5 on the nasal tissues.

Claim 58 The method according to claim 34 wherein the pH adjusting agent is selected from the group consisting of: sodium bicarbonate, sodium phosphate, sodium hydroxide, ammonium hydroxide, sodium stannate, triethanolamine, sodium citrate, and mixtures thereof.

Claim 59 The method according to claim 34 wherein the composition further comprises metal salts of metals selected from the group consisting of: zinc, copper, tin, silver, iron, aluminum, nickel, cobalt, manganese, and mixtures thereof.

Claim 60 The method according to claim 36 wherein the metal salt is selected from the group consisting of: acetates, ascorbates, chlorides, benzoates, citrates, gluconates, glutarates, lactates, malates, malonates, salicylates, succinates, and combinations thereof.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None